



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

PM-22
Cynthia Giles-Parker
Room 229

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA Reg. No./File Symbol: 1022-522 / Cunapsol-5

From: Ian Blackwell, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

QDB 11/17/93

To: Cynthia Giles-Parker, PM 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

*Thomas C. Ellwanger / bms
1-24-94*

Applicant: Chapman Chemical Company
P.O. Box 9158
Memphis, TN 38109

FORMULATION FROM LABEL:

Active Ingredient(s)::
Copper napthenate
Inert Ingredient(s):

	<u>% by wt.</u>
	45.4
	56.6
Total:	100.0%



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BACKGROUND: The Chapman Chemical Company has submitted an acute oral toxicity, acute inhalation toxicity and dermal sensitization studies in support of "Cunapsol-5". The registrant submitted these data as it was felt that they constituted 6(a)(2) data under FIFRA.

Two acute oral toxicity studies, a primary eye irritation study and a primary skin irritation study submitted in support of this product were previously reviewed by the FHB/TSS on 4/13/87. The results of the previous reviews were:

acute oral toxicity	III	guideline
acute oral toxicity		supplementary
primary eye irritation	I	minimum
primary skin irritation	I	guideline
dermal sensitization	guinea pig	guideline
	dermal sensitizer	

RECOMMENDATIONS:

The acute oral toxicity, acute inhalation toxicity and dermal sensitization studies are acceptable and are classified core-guideline data.

Note: No acute dermal toxicity study is required to support this product due to the toxicity category I primary skin irritation categorization of this product.

The acute toxicity profile for reg. no. 1022-522 is currently:

acute oral toxicity	III	guideline
acute dermal toxicity	not required	
acute inhalation toxicity	II	guideline
primary eye irritation	I	minimum
primary skin irritation	I	guideline
dermal sensitization	guinea pig	guideline
	dermal sensitizer	

LABELING:

1. The signal word is "DANGER" based on the primary eye and skin irritation studies.
2. The precautionary statements must state:

"Corrosive. Causes burns and irreversible eye damage. May be fatal if inhaled. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear goggles or face shield, protective clothing and rubber gloves. Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for

Occupational Safety and Health. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."

3. The statements of practical treatment should state:

"If in eyes: Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Call a physician."

"If on Skin: Wash with plenty of soap and water. Get medical attention."

"If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

"If swallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol. Get medical attention. Do not induce vomiting."

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

4. This product hits the trigger for Child Resistant Packaging due to acute inhalation toxicity, primary eye irritation and primary skin irritation. The PM Team should decide what course of action would best offset the hazards posed by this product.
5. This product hits the trigger for restricted use due to acute inhalation toxicity, primary eye irritation and primary skin irritation. The PM Team should decide if alternative labeling is sufficient to offset the need for restricted use classification and the hazards posed by this product.
6. This product is classified as an acute hazardous waste based on acute inhalation toxicity, primary eye irritation and primary skin irritation. The following statement must appear on the label:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1)

Product Manager: 22
MRID No.: 429715-01

Reviewer: Ian Blackwell *IOB 11/16/93*
Study Completion Date: 9/24/93
Study No.: 0318-93

Testing Facility: Stillmeadow, Inc.
Authors: Janice O. Kuhn, Ph.D.

Quality Assurance (40 CFR §160.12): Included.

Test Material: Cunapsol-5 (EPA reg. no. 1022-522); "dark green liquid"

Species: rat HSD:SD
Age: young adult Sex: 15 males + 20 females
Weight: males = 228-279 grams; females = 192-213 grams
Source: Harlan-Sprague Dawley

Conclusion:

1. LD₅₀ (mg/kg): Males = 1400 (800-2470)
 Females = 1180 (983-1410)
 Combined = 1240 (1010-1540)

2. Tox. Category: III Classification: core-guideline

Procedure (Deviations from §81-1):

Results:

Dosage (mg/kg)	(Number Killed/Number Tested)		
	Males	Females	Combined
1000	2/5	1/5	3/10
1200	*n.t.	2/5	2/5
1500	2/5	5/5	7/10
5050	5/5	5/5	10/10

Observations: Weight loss, diarrhea, activity decrease, lacrimation, nasal discharge, polyuria, salivation, ptosis, gasping and death.

Gross Necropsy: Signs of lacrimation, nasal discharge and/or salivation, stomach distended with blue fluid, stomach and/or gastrointestinal tract distended with gas, blue slurry in small and large intestines; lungs tan or mottled red; testes drawn into abdominal cavity,

*n.t. - not tested

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DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: 22
MRID No.: 429715-02

Reviewer: I. Blackwell *el DB*
Study Completion Date: 9/1/93
Study No.: 0319-93 *11/16/93*

Testing Laboratory: Stillmeadow, Inc.
Author(s): Mark S. Holbert

Quality Assurance (40 CFR §160.12): Included.

Test Material: Cunapsol-5; "dark green liquid"
Concentration:

Species: rat; HSD:SD
Weight: males = 229-281 grams; females = 191-228 grams
Age: young adult
Sex: 20 males + 20 females
Source: Harlan-Sprague Dawley

Summary:

1. **LC₅₀ (mg/l):** **Males** = 0.441 (0.260-0.747)
 Females = 0.438 (0.200-0.960)
 Combined = 0.440 (0.275-0.704)
2. **Tox. Category:** II **Classification:** core-guideline

Procedure (Deviation From §81-3):

Results:

Reported Mortality

Exposure Concentration	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
0.15 mg/L	0/5	0/5	0/10
0.39 mg/L	3/5	3/5	6/10
0.67 mg/L	3/5	4/5	7/10
1.50 mg/L	5/5	4/5	9/10

Chamber Atmosphere				
Dose Level (analytical)	MMAD	GSD	particles < 4.7 μm	particles < 3.3 μm
0.15 mg/L	1.883 μm	2.142 μm	77.58%	53.46%
0.39 mg/L	3.853 μm	4.018 μm	62.61%	45.34%
0.67 mg/L	2.75 μm	2.067 μm	59.81%	32.63%
1.50 mg/L	2.765 μm	2.349 μm	60.11%	35.97%

Chamber Environment	
Airflow	109 lpm
Temperature	72 °F
Relative Humidity	0.15 mg/L = 80% 0.39 mg/L = 91% 0.67 mg/L = 91% 1.50 mg/L = 92%

Clinical Observations: Aggression, activity decrease, staggered gait; weight loss; piloerection, fur coated with test material; alopecia; polyuria; prolapsed penis; death; nasal discharge; salivation; corneal opacity; gasping, and "respiratory chirp".

Gross Necropsy Findings: Lungs speckled brown or red, lungs mottled red, lungs slightly swollen; test material on fur; signs of nasal discharge, salivation, polyuria; G.I. tract distended with gas; spleen slightly undersized or 1/2 normal size.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6)

Product Manager: 22
MRID No.: 429715-03

Reviewer: Ian Blackwell
Study Completion Date: 9/14/93
Lab Project No.: 0320-93

11/17/93

Testing Laboratory: Stillmeadow, Inc.
Author(s): Janice O. Kuhn, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: CUNAPSOL-5
Positive Control Material: 1-Chloro-2,4-dinitrobenzene

Species: Hartley-albino guinea pig
Weight: males = 330-355g; females = 300-355g
Age: not specified
Source: SASCO

Method: Buehler Method

Summary:

1. This Product is a dermal sensitizer.
2. Classification:

Procedure (Deviation From §81-6):

Procedures: Irritation prescreening was conducted at 100%, 50%, 20%, and 5%. Induction was conducted using 0.4 ml of a 20% solution of test material in distilled water while challenge was conducted using 0.4 ml of a 5% solution of test material in distilled water. The animals received three induction treatments.

Results: Twenty-four hours after induction treatment #1, 4/10 test animals displayed strong erythema, 4/10 moderate erythema and 2/10 faint, usually confluent erythema. Twenty-four hours after induction treatments #2 and #3, 10/10 test animals displayed strong erythema.

Twenty-four hours after challenge with the test material, 6/10 test material-treated animals displayed moderate erythema and 2/10 displayed faint, usually confluent erythema. Twenty-four hours after challenge with the test material, no naive control animals displayed dermal irritation.

The only data from the positive control study was the mean challenge irritation scores from the positive control and naive challenge (with the positive control) animals. The mean naive challenge score was 0.1; the mean positive control challenge score was 1.2.

ACUTE TOX ONE-LINER

1. PC CODE: 023102
2. CURRENT DATE: 11/17/93
3. TEST MATERIAL: Copper napthenate ... 45.4%
EPA reg. no. 1022-522

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
acute oral toxicity / rat / Stillmeadow, Inc. / 0318-93 / 9-24-93	429715-01	LD ₅₀ males= 1400 (800-2470) females= 1180 (983-1410) combined= 1240(1010-1540)	III	G
acute inhalation tox. / rat / Stillmeadow, Inc. / 0319-93 / 9-1-93	429715-02	LC ₅₀ males= 0.441 (0.260-0.747) females= 0.438 (0.200-0.960) combined= (0.275-0.704)	II	G
dermal sensitization / guinea pig / Stillmeadow, Inc. / 0320-93 / 9-14-93	429715-03	Guinea pig dermal sensitizer.	---	G

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary